

## **4X MEDICATED SEVERE TOOTHACHE AND GUM GEL- benzocaine gel**

**Lornamead**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### **8015602 4x Med Gel**

Benzalkonium chloride 0.13% . . . Oral antiseptic

Benzocaine 20% . . . Oral pain reliever

Menthol 0.5% . . . Oral pain reliever

Zinc chloride 0.15% . . . Oral astringent

Use \* for the temporary relief of pain due to toothaches \* to help prevent against infection of minor oral irritation

Methemoglobinemia warning: use of this product may cause methemoglobinemia, a serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. This can occur even if you have used this product before. Stop use and seek immediate medical attention if you or a child in your care develops: \* pale, gray, or blue colored skin (cyanosis) \* headache \* rapid heart rate \* shortness of breath \* dizziness or lightheadedness \* fatigue or lack of energy

Allergy alert: do not use this product if you have a history of allergy to local anesthetics such as procaine, butacaine, benzocaine or other "caine" anesthetics

Do not use \* more than directed \* for more than 7 days unless told to do so by a dentist or doctor \* for teething \* in children under 2 years of age

Stop use and ask a doctor if \* swelling, rash or fever develops \* irritation, pain or redness persists or worsens \* symptoms do not improve in 7 days \* allergic reaction occurs

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions \* cut open tip of tube on score mark \* adults and children 2 years of age and older: apply a small amount of product to the cavity and around the gum surrounding the teeth. Use up to 4 times daily or as directed by a dentist or doctor \* children under 12 years of age should be supervised in the use of this product \* children under 2 years of age: do not use

Other information \* do not use if tip of tube is cut prior to opening \* this preparation is intended for use in cases of toothache, only as a temporary expedient until a dentist can be consulted \* do not use continuously \* this formula will stay in place for extended duration of relief \* avoid using toothpaste or drinking soft drinks or fruit juices for at least one hour after applying

ammonium glycyrrhizate, blue 1, flavor, PEG-8, PEG-75, sodium saccharin, sorbic acid



1.031 X 1.031 X 3.500 - PRINTSIDE  
FOIL S170274 - 3/9/17







CMYK: CYAN, MAGENTA, YELLOW, BLACK  
 RGB: RED, GREEN, BLUE  
 PANTONE: 100, 200, 300, 400, 500, 600, 700, 800, 900, 1000

FILE NAME	ITEM NUMBER	PRINT PROCESS
933633_CVSHHealth_Craquel_4XMed_ToothacheGel_CARTON.ai	933633	OFFSET LITHO
PRODUCT #	ITEM #	DATE
190608125	LORNAMEAD	11/04/19
USER/DESIGN #	DESIGN #	DESIGNER
050428251041	PC1 BOARD	MSN








































































































































LORNAMEAD, INC.		PROJECT INFO   PRODUCTION NOTES	
DATE:	DECEMBER 20, 2019		<b>APPROVALS</b> CREATIVE _____ MARKETING _____ R&D _____ QUALITY _____ PURCHASING _____ CEO _____
PROJECT:	CVS 4X MEDICATED TOOTHACHE GEL CARTON		
ITEM #:	2821602R1		
DIELINE #:	S170274		
SIZE:	1031" X 1.031" X 3.500"		
FILE NAME:	CVS_4XMEDICATED_TOOTHACHEGEL_CTN_2821602R1-OLAI		
PRINTER:	MODPAC		
NOTE(S):			

## benzocaine gel

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62721-5602	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
ZINC CHLORIDE (UNII: 86Q357L16B) (ZINC CATION - UNII:13S1S8SF37)		ZINC CATION	0.15 g in 100 g	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)		BENZALKONIUM CHLORIDE	0.13 g in 100 g	
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)		BENZOCAINE	20 g in 100 g	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A) (MENTHOL, UNSPECIFIED FORM - UNII:L7T10EIP3A)		MENTHOL, UNSPECIFIED FORM	0.5 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
METHYL SALICYLATE (UNII: LAV5U5022Y)				
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)				
SORBIC ACID (UNII: X045WJ989B)				
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)				
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)				
Product Characteristics				
Color	blue	Score		
Shape		Size		
Flavor	WINTERGREEN	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62721-5602-9	7.1 g in 1 TUBE; Type 0: Not a Combination Product	06/05/2020	
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
OTC monograph not final	part356		06/05/2020	

**Labeler** - Lornamead (126440440)

**Registrant** - Lornamead (080046418)

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Establishment			
Name	Address	ID/FEI	Business Operations
Lornamead		080046418	manufacture(62721-5602)

Revised: 6/2020

Lornamead